(c) Health being a State Subject, the concerned State Governments take necessary steps to control any incidence of Anthrax. The Central Government provides technical support whenever required.

**Rules for testing of drugs on humans**

2531. SHRI A. VIJAYA RAGHGAVAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware of the drug tests on human beings;

(b) if so, the details thereof;

(c) whether the above drug tests and their impact on human beings is as per rules and with the approval of Competent Authority;

(d) if so, the details of such voluntary human experimentation conducted by the pharmaceutical companies and money given to volunteers, if any, in the last three years, State-wise and year-wise; and

(e) the details of rules and regulations to test drugs and their impact on human beings?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIMATI SUSHMA SWARAJ): (a) to (e) Yes, Sir. The new drug development procedures involve study of drugs on human subjects at various phases of clinical trials. In India, specific provisions have been laid under Rules 122-A and B, and Schedule Y of Drugs and Cosmetics Rules for test of new drug on human subjects. Such drug trials/tests are required to be conducted with due approval of competent authority under Rule-21 of Drugs and Cosmetic Rules. also guidelines on Good Clinical Practice (GCP) and Ethical Guidelines for Bio-medical research on human subjects have been framed. The regulatory procedure does not involve monitoring of money, if any paid to the volunteers.